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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,919	11/19/2003	Paul Bruschi	2003P00794US01	6419

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Siemens Corporation
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EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	PAPER NUMBER
3626	
MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,919	BRUSCHI ET AL.	
	Examiner	Art Unit	
	DILEK B. COBANOGLU	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6,7,9-11,24-27,30,31 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6,7,9-11,24-27,30,31 and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This communication is in response to the amendment received on 01/06/2009. Claims 12-14, 17-19 and 21-23 have been canceled, claims 36-37 are newly added. Claims 1-3, 6-7, 9-11, 24-27, 30-31 and 33-37 remain pending in this application.

Claim Objections

2. Claim 35 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 35 recites "wherein the data exchange service performs a one-way hash on the identities of the patients to create encrypted versions of the patient identities"; "encrypting the patient identities" was deleted in the independent claim 24, and has been replaced by "secure patient codes". Therefore, Examiner considers that the term "encrypted version" was forgotten to be amended and appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 2, 3, 6, 10, 11, 24-27, 30, 34, 35, 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (US Patent Publication No.

2002/0099570), Uchikubo (2003/0046562 A1) and further in view of Saeed et al. (hereinafter Saeed) (US. Patent No. 6,915,266).

A. Claim 1 has been amended now to recite a method for identifying clinical trial candidates (see abstract of Knight), the method comprising the steps of:

i. receiving at a data exchange service from a patient clinical data source, patient data including identities of patients (Knight; abstract, paragraphs:0005, 0052, 0058);

ii. replacing the identities of the patients in the patient data with secure patient codes;

iii. forwarding the patient data with secure patient codes, from the data exchange service to a clinical trial candidate identification service (Knight; abstract, paragraphs:0005, 0058, 0125); and

iv. receiving at a data exchange service from the clinical trial candidate identification service a clinical trial candidate proposal including a secure patient code corresponding to a proposed clinical trial candidate for a clinical trial (Knight; abstract, paragraphs:0005, 0050, 0053, 0058);

v. determining an identity of the proposed clinical trial candidate from the secure patient code (Knight; abstract, paragraphs: 0050, 0053, 0058); and

vi. forwarding the identity of the proposed clinical trial candidate from data exchange service to a candidate contact (Knight; abstract, paragraphs:0005, 0058); and

vii. forwarding from the clinical trial candidate identification service to the candidate contact, descriptive information about the clinical trial;

viii. wherein the clinical data source is a database containing transactions between healthcare providers and payers. Knight teaches "forwarding the identity of the proposed clinical trial candidate to a candidate contact" (Knight; abstract, paragraphs:0005, 0058);

Knight fails to expressly teach replacing the identities of the patients in the patient data with secure patient codes, per se since Knight is directed to "keeping patient information protected from unauthorized access (par. 0061). However, this feature is well known in the art, as evidenced by Uchikubo.

In particular, Uchikubo discloses replacing the identities of the patients in the patient data with secure patient codes (Uchikubo; abstract, paragraphs: 0010, 0038, 0079).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Uchikubo with the motivation of maintaining security and protect patient's personal information (Uchikubo; 0038).

Knight fails to explicitly teach the method wherein the database contains transactions. Saeed, however, teaches a method which

has a database containing transactions between health care providers and payers (see column 9, lines 21-29 of Saeed et al.). It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight. One of ordinary skill in the art would have been motivated to combine these features in order to conduct audits and information tracking (see column 9, lines 28-29 of Saeed).

B. As per claim 2, Knight discloses the method wherein the candidate contact is a health care provider of the candidate (Knight; paragraph 0052).

C. As per claim 3, Knight discloses the method of claim 1 as described above. Knight further teaches the method wherein the candidate contact is the proposed clinical trial candidate (Knight; paragraph 0070).

D. As per claim 6, Knight discloses the method further comprising the step of extracting patient medical information from the patient data received from a patient clinical data source (Knight; abstract, paragraphs: 0005, 0021, 0058).

E. As per claim 10, Knight teaches the method of claim 1 as described above. Knight further teaches the method further comprising the steps of: receiving from the candidate contact a status of the clinical trial candidate proposal (Knight; paragraph: 0070); and forwarding the status to the clinical trial candidate identification service (Knight; paragraph: 0070).

F. Claim 11 has been amended now to recite the method of claim 10 wherein the status includes the identity of the proposed candidate and the method further

comprises the step of replacing the identity of the proposed candidate with a secure patient code before forwarding the status to the clinical trial candidate identification service (Knight; paragraph: 0061, 0070).

G. Amended claim 24 recites a system for identifying clinical trial candidates, comprising:

i. a data exchange service for receiving patient records from a patient clinical data source and replacing identities of patients in each patient record with a secure patient code (Knight; abstract, paragraphs:0005, 0050, 0052, 0053, 0058);

ii. a clinical trial candidate identification service for receiving the patient records with secure patient codes from the data exchange service (Knight; abstract, paragraphs:0005, 0050, 0053, 0058),

iii. identifying a patient record as a clinical trial candidate for a clinical trial, forwarding the secure patient code of the identified patient record to the data exchange service, and forwarding information about the clinical trial to a candidate contact (Knight; paragraphs:0005, 0050, 0053, 0056, 0058, 0125, 0126);

iv. the data exchange service being further for determining an identity of a patient from the secure patient code of the identified patient record, and forwarding the identity of the patient to the candidate contact (Knight; paragraphs:0005, 0050, 0052, 0053, 0056, 0058, 0061, 0125, 0126);

v. wherein the clinical data source is a database containing transactions between health care providers and payers.

The obviousness of modifying the teaching of Knight to include the transactions between health care providers and payers (as taught by Saeed) is as addressed above in the rejection of claim 1 and incorporated herein.

H. Claim 25 has been amended now to recite the system of claim 24, wherein the clinical trial candidate identification service forwards a secure patient code of the identified patient record to the data exchange service, and the data exchange service determines the identity of the patient and forwards the identity to the candidate contact for contacting the patient (Knight; paragraphs: 0005, 0050, 0052, 0053, 0056, 0058, 0061, 0125, 0126).

I. Claim 26 has been amended now to recite the system of claim 24, wherein the data exchange service receives a status of the clinical trial candidate proposal, replaces an identity of the proposed candidate with a secure patient code; and forwards the status to the clinical trial candidate identification service (Knight; paragraphs: 0005, 0050, 0052, 0053, 0056, 0058, 0061, 0125, 0126).

J. Claim 27 recites the system of claim 24, wherein the clinical trial candidate identification service is further for receiving candidate selection criteria for a clinical trial, and the clinical trial candidate identification service identifies a patient record based on the candidate selection criteria (Knight; paragraphs: 0005, 0050, 0052, 0053, 0056, 0058, 0061, 0125, 0126).

K. Claim 30 recites the system of claim 24, wherein the data exchange service is further for extracting patient medical information from the patient data received from a patient clinical data source (Knight; paragraphs: 0050, 0052).

L. Claim 34 has been amended now to recite the method of claim 1, wherein the step of replacing the identities of the patients in the patient data with secure patient codes further comprises: performing a one-way hash.

Knight fails to expressly teach performing a one-way hash.

However, this feature is well known in the art, as evidenced by Saeed.

In particular, Saeed discloses performing a one-way hash (or hash algorithms) (Saeed; col. 8, lines 15-37).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Saeed with the motivation of adding security measures to strengthen the system (Saeed; col. 8, lines 15-37).

M. Claim 35 recites the system of claim 24, wherein the data exchange service performs a one-way hash on the identities of the patients to create encrypted versions of the patient identities.

The obviousness of modifying the teaching of Knight to include one-way hash (or hash algorithm) (as taught by Saeed) is as addressed above in the rejection of claim 34 and incorporated herein.

N. Newly added claim 36 recites the method of claim 1, wherein the step of replacing the identities of the patients in the patient data with secure patient codes comprises encrypting the identities to create secure patient codes, and the step of determining an identity of the proposed clinical trial candidate comprises decrypting the secure patient code corresponding to the proposed clinical trial candidate.

Knight fails to expressly teach replacing the identities of the patients in the patient data with secure patient codes comprises encrypting the identities to create secure patient codes, and the step of determining an identity of the proposed clinical trial candidate comprises decrypting the secure patient code corresponding to the proposed clinical trial candidate. However, this feature is well known in the art, as evidenced by Uchikubo.

In particular, Uchikubo discloses "Patient data including identification information, a name and so on relating to a patient is encrypted in an encrypting portion and then is sent. In the remote control room side receiving the patient data through the communication circuit, the patient data is decrypted by a decrypting portion when it is determined, based on the header portion, that the received data includes the patient data." (abstract), and "…when patient data is encrypted, an identifier code 84 indicating that the patient data is encrypted is added to the header portion 72

(Uchikubo; 0113, 0114). It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Uchikubo with the motivation of maintaining security and protect patient's personal information (Uchikubo; 0038).

O. Newly added claim 37 recites the method of claim 1, The method of claim 1, wherein the step of replacing the identities of the patients in the patient data with secure patient codes comprises replacing the identities with unique codes and maintaining a table correlating the identities with the unique codes, and the step of determining an identity of the proposed clinical trial candidate comprises looking up in the table an identity of a patient corresponding to the secure patient code.

The obviousness of modifying the teaching of Knight to include replacing the identities of the patients in the patient data with secure patient codes (as taught by Uchikubo) is as addressed above in the rejection of claim 36 and incorporated herein.

Also, Examiner notes that "maintaining a table correlating the identities with the unique codes, and the step of determining an identity of the proposed clinical trial candidate comprises looking up in the table an identity of a patient corresponding to the secure patient code" would be done by keeping these information in

database, either in a table or spreadsheet or in a list. Since Knight and Uchikubo both have databases, and Uchikubo keeps a record of patient identities and patient codes, they are not necessarily in a table, but could be a list or spreadsheet.

5. Claims 7 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (US Patent Publication No. 2002/0099570), Saeed et al. (hereinafter Saeed) (US. Patent No. 6,915,266) and further in view of Thangaraj et al. (hereinafter Thangaraj), (US. Patent Publication No. 2003/0208378).

A. As per claim 7, Knight and Saeed teach the method of claim 1 as described above.

However, none of the references explicitly teach the method of reformatting the data. Thangaraj, however, does teach the method comprising the step of reformatting the patient data received from a patient clinical data source (Thangaraj; paragraph 0019).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate this feature into the methods of Knight, Uchikubo, and Saeed et al. One of ordinary skill in the art would have been motivated to combine these features to allow data to be captured from and provided to a number of different data sources regardless of data format (Thangaraj; paragraph 0019).

B. System claim 31 repeats the subject matter of claim 7 as a set of "means-plus- function" elements rather than a series of steps. As the underlying process

has been shown to be fully disclosed by the teachings of Knight, Saeed, and Thangaraj in the above rejection of claim 7, it is readily apparent that the Knight, Saeed, and Thangaraj references include a system to perform the recited functions. As such, these limitations are rejected for the same reasons provided in the rejection of claim 7 and incorporated herein.

6. Claims 9 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Knight (US Patent Publication No. 2002/0099570), Saeed et al. (hereinafter Saeed) (US. Patent No. 6,915,266) and further in view of Thomas et al. (hereinafter Thomas) (US. Patent Publication 2004/0078238).

A. As per claims 9 and 33, Knight teaches the method of claim 1 and system of claim 24 as described above.

Knight fails to expressly teach a hospital network. However, Thomas teaches a hospital network (Thomas; paragraphs; 0002, 0010).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Thomas with the motivation of to be able to properly support research and development (Thomas; 0002).

Response to Arguments

7. Applicant's arguments filed 1/6/2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear.

A. In response to Applicant's argument about neither Knight nor other references teach "an identity of patient and information about the clinical trial are forwarded separately by different entities to a candidate contact"; Examiner respectfully submits that the present application recites: "…It is only when a trusted patient contact such as the patient's healthcare professional contacts the CTCIS directly that the patient contact will have any further information available about the selection of the patient as a candidate. Only at that point will information about the proposed clinical trial be available. (Par. 0052)" and "…Contact information 460 is sent on to the candidate contact (healthcare professional) informing the contact that a patient may qualify for a clinical trial and giving specific contact information at the CTCIS. Once the healthcare professional contacts the CTCIS with a request for trial information 470, further details 480 about the clinical trial can be given. (Par. 0053)", also in figures 1 and 4 indicate this request for information from the healthcare provider, then the healthcare professional receives information from a database, therefore the healthcare professional contacts the CTCIS to get the details of clinical trail. Knight teaches: par. [0052] In an embodiment, the patient, or clinician on behalf of the patient, inputs information … into the patient interface. And par. [0126] In an embodiment, the security application layer also sanitizes the information passed on to the client system. .. For proprietary trials, unless otherwise specified, the security protocols ensure that all confidential, proprietary trial details are hidden. Only trial contact information is displayed on the web.

Therefore the patient or healthcare professional contacts the trial contact to get the detailed clinical trial information.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

9. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

12. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Dilek B Cobanoglu/
Examiner, Art Unit 3626
4/1/2009

/Robert Morgan/
Primary Examiner, Art Unit 3626